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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,626	11/26/2003	Daniel Pratt	19043-501	9707

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,626	PRATT ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/4/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 4-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2 and 4-41 are pending. Claims 1, 10, 12-15, and 22 have been amended. Applicants previously cancelled claim 3. Receipt and consideration of Applicants' amended claim set, remarks/arguments submitted on December 4, 2006 is acknowledged. Applicants' claim amendments requiring a particle size of 1-100 microns necessitated new rejections under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Upon reconsideration, the rejection of claims 13-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicants' persuasive arguments.

Response to Arguments

Applicant's arguments, see page 9, filed December 4, 2006, with respect to the rejection of claims 13-15 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 13-15 under 35 U.S.C. 112, second paragraph has been withdrawn.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2, 6, 10, 16, and 34 under 35 U.S.C. 102(b) as being anticipated by Penners et al. (US Patent No. 6,306,439) (USPN '439) **is withdrawn**, per Applicants' amendments to claim 1 requiring that the claimed particles have a particle size of 1-100 microns.

Response to Arguments

Applicant's arguments, see pages 9-10, filed December 4, 2006, with respect to the rejection of claims 1-2, 6, 10, 16, and 34 under 35 U.S.C. 102(b) have been fully considered and are persuasive. The rejection of claims 1-2, 6, 10, 16, and 34 under 35 U.S.C. 102(b) has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 12-31, 35, 37-38, and 40-41 under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,455,044) in view of Penners et al. (US Patent No. 6,306,439) (USPN '439) **is maintained** for the reasons of record set forth on pages 6-11 and 4-5, respectively, of the office action mailed on June 2, 2006. Claims 1-2, 4-10, 16, and 34 are appended to this rejection. In summary, **claims 1-2, 4-10, 12-31, 34-35, 37-38, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,455,044) in view of Penners et al. (US Patent No. 6,306,439) (USPN '439).**

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,455,044) in view of Penners et al. (US Patent No. 6,306,439) (USPN '439) as applied to claims 1-2, 4-10, 12-31, 34-35, 37-38, and 40-41 above, and further in view of

Chen et al. for the reasons of record set forth on pages 11-13 of the office action mailed on June 2, 2006.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,455,044) in view of Penners et al. (US Patent No. 6,306,439) (USPN '439), in view of Chen et al. as applied to claims 1-2, 4-10, 12-31, 34-35, 37-38, and 40-41 above, and further in view of Hatcher et al. for the reasons of record set forth on pages 13-15 of the office action mailed on June 2, 2006.

Claims 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (U.S. Patent No. 5,455,044) in view of Penners et al. (US Patent No. 6,306,439) (USPN '439) as applied to claim 1-2, 4-10, 12-31, 34-35, 37-38, and 40-41 above, and further in view of Russell et al. for the reasons of record set forth on pages 15-17 of the office action mailed on June 2, 2006.

Response to Arguments

Applicant's arguments filed December 4, 2006 have been fully considered but they are not persuasive. Applicants' traversal of the above cited rejections under 35 U.S.C. § 103(a) are based on their assertion that the Kim and Penners references are not combinable, because an ordinary skilled artisan would know that hydrogen carbonates generate hydroxide ion upon contact with water or aqueous solutions and that hydroxide ion is toxic. This is found unpersuasive, because although hydroxide ion in very high concentrations may have negative

physiologic consequences Applicants' have provided no evidence that the amount of hydroxide generated would be toxic in the CSF and therefore discourage an ordinary skilled artisan from combining the Kim and Penners references. Furthermore, it is noted that Applicants have stated that CSF fluid is typically maintained at a pH of 7.35. At a pH of 7.35, CSF would contain hydroxide ions; therefore, the mere presence of hydroxide ion is not sufficient for one to conclude that a toxic formulation would result. CSF, blood, and many other biological fluids, which are not excreted, are typically buffered aqueous formulations and as a result are characterized as being capable of resisting large changes in pH. It is noted that the combined prior art also teaches that the hydrogen carbonates may also be combined with acids (e.g. citric acid). It is the Examiner's position that any potentially harmful levels of hydroxide would be neutralized by the acids that are co-formulated with the hydrogen carbonates. Regarding the introduction of a limitation of a particle size of 1-100 microns for the claimed compositions, it is noted that Kim teaches particles having particle sizes ranging from 20 nm to 50 microns (see page 8 of the office action mailed on June 2, 2006). Because the range taught by Kim overlaps with that claimed by Applicants, the claimed particle size is obvious. Therefore, for the aforementioned reasons Applicants' arguments are unpersuasive and the rejections under 35 U.S.C. § 103(a) based upon the Kim and Penners references are deemed appropriate and are maintained.

Conclusion

Claims 1-2 and 4-41 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

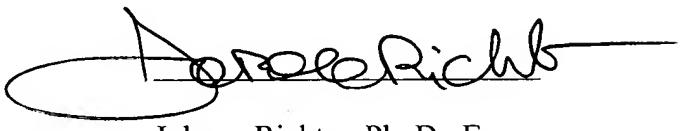
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
Technology Center 1600



Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
Technology Center 1600